IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re of Application of:	Gary S. Grubb		
Serial No.:	09/872,250	Group Art No.:	1617
Filed:	June 1, 2001	Examiner:	S. Hui
For:	Starter Kit for Low Dose Oral Contraceptives		
Confirmation No.:	4735		
Customer Number:	25291		

Assistant Commissioner for Patents
Washington, DC 20231

Sir:

AMENDMENT TRANSMITTAL LETTER

1. Enclosed please find the following documents for the above-identified application: Response to Office Action mailed on August 24, 2001.

2. Fee calculation

CLAIMS AS AMENDED					
(1) FOR	(2) CLAIMS REMAINING AFTER AMENDMENT	(3) HIGHEST NUMBER PAID FOR	(4) NUMBER EXTRA x RATE		(5) ADDITIONAL FEE
TOTAL CLAIMS	11	11	0	x $ 18.00	0.00
INDEPENDENT CLAIMS	1	1	0	x $ 84.00	0.00
MULTIPLE DEPENDENCY FEE	0	0	0	$ 280.00	0.00
			Total Amendment Fee:		$0.00

☒ Please charge Deposit Account No. 01-1425 for: $0.00

The Commissioner is hereby authorized to charge any additional fees required by this paper, including the enclosed documents, and during the entire pendency of this application and to credit any excess amounts paid to Deposit Account No. 01-1425. A copy of this letter is enclosed for use by the Deposit Account Branch.

Respectfully submitted,

Arnold S. Milowsky
Attorney for Applicants
November 21, 2001
Reg. No. 35,288

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Serial No.: 09/872,250 **Examiner:** Hui

Filed: June 1, 2001 **Group:** 1617

For: Starter Kit for Low Dose Oral Contraceptives **Confirmation No.** 4735

Assistant Commissioner of Patents
Washington, DC 20231

RESPONSE UNDER RULE 111

Sir:

Claims 1-11 are in the application and stand rejected; after entry of this amendment, Claims 1-11 will remain in the application.

Claims 1-11 stand rejected under 35 USC 103 as being obvious over the Physicians' Desk Reference (Nordette and Alesse monographs; hereinafter collectively referred to as PDR), in view of Katzung, and Endrikat. For the reasons provided below, the applicant respectfully traverses the rejection, and submits that the USPTO has not even made out a case of prima facie obviousness.

The overriding law in determining whether a claimed invention is obvious over the prior art requires that an analysis must be undertaken based on several factual inquiries which include: "(1) the scope and content of the prior art; (2) the difference between the prior art and the claims at issue; (3) the level of ordinary skill in the art at the time the invention was made; and objective evidence of nonobviousness, if any." In re O'Farrell 7 U.S.P.Q.2d 1673, 1680 (1988) (citing Graham v. John Deere Co. 383 U.S. 1, 17-18 (1966)). An analysis of the prior art in relation to the claimed invention is provided below.

Applicant's Invention

The applicant's claims cover a contraceptive starter kit which contains at least two or more cycle packs of oral contraceptive having a higher dosage, than the effective

contraceptive dosage that is subsequently given to maintain contraceptive protection. The starter pack is to be administered before the normal contraceptive regimen is administered. The problem that the applicant was trying to solve is that the incidence of unwanted breakthrough bleeding and spotting is higher during the first few cycles of contraceptive administration than is observed during the subsequent cycles. This increased incidence of breakthrough bleeding and spotting during the initial cycles is highly undesirable. The applicant discovered that administering a contraceptive at a higher dosage during at least the first two cycles decreases the incidence of breakthrough bleeding and spotting, thereby solving the problem at hand.

Prior Art

The Nordette monograph teaches an oral contraceptive composition containing 0.15 mg levonogestrel (LNG) plus 30 µg ethinyl estradiol (EE). There is nothing in the monograph which teaches or even remotely suggests administering a higher dosage of contraceptive during at least the first two cycles to minimize breakthrough bleeding and spotting (or for any purpose at all). The reference teaches only one dosage regimen, that is administered every cycle.

The Alesse monograph teaches an oral contraceptive composition containing 0.1 mg LNG plus 30 µg EE. There is nothing in the monograph which teaches or even remotely suggests administering a higher dosage of contraceptive during at least the first two cycles to minimize breakthrough bleeding and spotting (or for any purpose at all). The reference teaches only one dosage regimen, that is administered every cycle.

Katzung teaches the use of norethindrone, norethindrone acetate, and norgestimate in contraceptive regimens. Again, there is nothing in the monograph which teaches or even remotely suggests administering a higher dosage of contraceptive during at least the first two cycles to minimize breakthrough bleeding and spotting (or for any purpose at all).

Endrikat teaches a contraceptive composition containing 20 µg EE plus 75 µg gestodene. Again, there is nothing in the monograph which teaches or even remotely suggests administering a higher dosage of contraceptive during at least the first two cycles to minimize breakthrough bleeding and spotting (or for any purpose at all).

Analysis

The applicant respectfully submits that the is nothing in any of the reference that singularly or collectively teaches or even remotely suggests administering a higher dosage of contraceptive during at least the first two cycles to minimize breakthrough bleeding and spotting (or for any purpose at all). The starter kit containing the higher dosage during at least the first two cycles is the applicant's claimed invention. It is clearly not taught or suggested by the prior art.

In the Office Action dated August 24, 2001, it is stated that it "would have been obvious to one skilled in the art when the invention was made to incorporate both Nordette and Alesse together with a written description of how to take the contraceptive into a kit for oral contraception." Similar statements are made relative tot he other progestins. It appears that the USPTO is taking the position that it would be obvious for one skilled in the art to take several cycles of Nordette followed by switching to Alesse to achieve the applicant's claimed invention. The applicant respectfully submits that this is clearly a hindsight reconstruction of the applicant's claimed invention. There is nothing in any of the references which suggests using a higher dosage of contraceptive for at least the first two cycles. The USPTO is merely picking and choosing parts of the invention first disclosed by the applicant to make a hindsight reconstruction of the applicant's invention from the prior art. This is clearly improper, and has never been the basis for an obviousness rejection.

The law on obviousness is fairly straightforward (although its application often isn't). Obviousness requires motivation. For obviousness to lie over a reference, one skilled in the art must be motivated to make the invention in question based on something that is specifically taught in the reference. As discussed above, there is nothing contained in any of the references which would motivate one skilled in the art to give anything other than the same dosage each cycle. The references provide no motivation to give a higher dosage for at least one cycle. Reconsideration is respectfully requested.

Accordingly, the applicants respectfully request reconsideration of the rejections and allowance of Claims 1-11, and passage of the case to issue.

Respectfully submitted,

Dated: November 21, 2001
Telephone: (610) 902-2635

Arnold S. Milowsky
Reg. No. 35,288